REMARKS

Claims 1 through 11 still remain in this application. Claims 4 and 9 are amended to remove the term "engaging". Applicant's attorney apologizes for the insertion of this term inasmuch as it was deleted from the original draft of the application and due to an inadvertent error, it wasn't deleted from the word processor and hence, was carried over into the original claims 4 and 9. In view of this amendment, it is believed that the 35 U.S.C. § 112, second paragraph objection should be removed.

Claims 12 through 32 are newly added in the belief that they patentably distinguish over the cited references and the art known to applicant for the reasons that will become apparent from the discussion to follow.

The drawing has been amended to include a new reference numeral to replace a reference numeral that was duplicated.

Before advancing arguments in rebuttal to the Examiner's rejection of all the claims it is believed note worthy to discuss the nature of the present invention. As the Examiner must be aware, the term "dilation" means to widen or to expand. In surgical parlance, the term is often used in medical procedures performed on women, namely dilation and curettage (D&C) and dilation and evacuation (abortion). It is also a term well known in minimally invasive surgery, such as spine surgery where the access to the cite being operated on is widened to provide the space for the surgeon to perform the surgery. In prior hereto known surgery, the surgeon would make an incision and insert a guide wire into the incision and the guide wire being a cutting instrument with a cutting tip be directed toward the target and hence and the surgeon would then, insert a dilator over the guide wire and continue to insert other dilators over each previous dilators until the opening is

sufficiently wide to perform the operation through the bore of the cannula. Thus, a dilator includes a central passage or lumen. Hence, the term non cannulated dilator by definition defines an instrument that is a 1) dilator and 2) does not include the central passage. Since a guide wire is, indeed, not a dilator, it is automatically precluded as a non-cannulated dilator.. In other words, placing a dilator, a wire and non cannulated dilator in front of a surgeon, the surgeon would be able to pick out each of these instruments merely by telling the surgeon the name of the instrument.

The Examiner cites three different patents and uses two to reject all the claims. All three will be discusses herein. Because of the nature of the instruments described in each patent, it is suggested that the description of the application leaves something to be desired or conveyed the wrong meaning to the Examiner or perhaps, the Examiner doesn't appreciate the nature of this invention. In other words, the Examiner cites references to medical procedures that utilize 1) guide wires, 2) dilator bougie and 3) trocars. Trocars are utilized primarily to puncture and create an incision in the abdomen of a patient. The trocar includes a trocar needle that has a sharp-pointed front end that performs a cutting operation. The dilator bougie is a flexible tube (lumen) and indeed, is not a non cannulated dilator and the guide wire is essentially a cutting instrument that was described in the background section of the patent application and is quoted below for the convenience of the Examiner.

> "As is well known .... a guide wire with a sharpened tip to purcutaneously pass through the muscle and engage a target of bone or vertebral disc is typically used. The first dilator is then passed over the guide wire and down to the target. Unfortunately, this method is fraught with a potential danger to the patient. Because the guide wire is relatively thin where it is able to pass through the muscle and ligamentous anatomy, it can protrude into the spinal canal and hence, cause injury to the delicate neural anatomy. If the misplaced guide wire is not detected before the dilators are inserted, catastrophic

injury, such as permanent disablement of the patient can occur."

The present invention was conceived to solve the problems created by the guide wire. The present invention doesn't cut through the skin, or tissue or muscles etc, but rather it dilates. Namely, the non cannulated dilator serves to part the muscle fibers to define a surgical plane. Normally, the body includes natural surgical planes. However, where the fibers are in the path of the target it is necessary to define a plane for the surgeon to have access to the target. Thus, references to trocars, guide wires and dilator bougie are misplaced and are not pertinent to the present invention.

While the invention is recited in broad terms, it is believed that the inventor has contributed a new instrument that solves difficult problems inherent in the instruments it replaces and is entitled to these broad claims, particularly in view of the cited references.

Reconsideration of the rejection of claims 1-4, 6-9 and 11 under 35 U.S.C. § 102(b) as being anticipated by Osada (6,162,236). As the Examiner is aware, the Osada reference relates to a trocar and a trocar is not a dilator. Independent claims are limited to dilators. The trocar needle has a sharp point that when it is thrust into the body wall, it makes an incision in the patient's body wall and proceeds to open the cavity of the patient. This instruments performs a cutting operation which is counter to the surgical procedure of the present invention. As mentioned above, the non cannulated dilator serves to part the muscle fibers and create surgeon directed tissue planes when the instrument is inserted into the body through an incision that was previously made to reach the target area. Once this is accomplished, the additional dilators are inserted over the non cannulated dilator. It is well known that dilators are not used to make incisions in the body wall. Moreover, this claim limits the non cannulated dilator to "afford a resistive force" while being inserted toward the target. This

language means that the tip of the instrument is intended not to cut into the members in front of it but rather to push them aside. Claim 1has been amended to make it clear that the tip is blunted and is not a cutting tip. As the Examiner is aware in order for a cited reference to be anticipatory, it must include all the elements recited in the rejected claim. It is earnestly submitted that this reference does not include all the elements and as a matter of fact it is a different instrument from that being claimed and the § 102(b) rejection should be withdrawn.

Claims 1 and 5 were similarly rejected on 35 U.S.C. § 102(b) but as being anticipated by Pattison (6,162,236). It is respectfully submitted that this reference is not pertinent. The Pattison structure is a dilator bougie. A bougie is a flexible instrument and this instrument is intended to be used in the esophagus which is an entirely different procedure than where a rigid dilator would be used. Moreover, the esophageal dilator bougie described in Pattison includes a central lumen. Claim 1 is limited to a solid and rigid body. The term non-cannulated itself means that there is no lumen in the instrument. It is difficult to comprehend how the Examiner rejected this claim as being anticipated inasmuch as both instruments are so different and it is submitted that this rejection should be withdrawn.

Reconsideration of the rejection of claim 10 as being unpatentable over Osada in view of Pattison in light of35 U.S.C. § 103(a) is respectfully requested. Patentability is not predicated on the indicia recited in claim 10, but rather on the combination of the indicia and the non cannulated dilator. As mentioned in the above paragraph with respect to claim 7 which is applied with equal vigor in this rebuttal, the Osada patent is directed to a trocar and the trocar needle is not a non cannulated dilator. The trocar is a cutting instrument intended to cut through the body wall of the patient.

Claims 12 through 32 are added to the application because it is believed that the method utilizing the non cannulated dilator is patenable over the cited references and the prior art known to applicant. It will be appreciated that the non cannulated dilator is applied after the incision is made and is used to reach the proximity of the vertebra, which is the target where the surgical procedure is being performed. Thus as is limited in claim 12, the non cannulated dilator is inserted into the incision made on the skin of the patient, and is moved into proximity of the vertebra and the proximate end extends outside where dilators are inserted over the non-cannulated dilator until a cannula inserted over the dilator that has a sufficient working channel is applied to allow the surgeon to perform the intended surgical procedure. As argued with respect to the other claims, none of the references teach the use of a non cannulated dilator, nor do they teach or suggest inserting this instrument in proximity to or in contact with the vertebra.

In view of the foregoing, it is believed that this application is in condition for allowance and the allowance thereof is respectfully requested.

Respectfully submitted,

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